2. Summary of Safety and Effectiveness Information

K050457

MAR 1 - 2005

Submitted by:	**Merete Medical GmbH** **Alt Lankwitz 102, 12247 Berlin** **Germany**
FDA Registration Number:	**3002949614**
Contact Person:	**Jenik Radon,** **269 West Seventy-First Street** **New York, N.Y. 10023** **Tel. 212- 496-2700 Fax 212- 724-3393**
Device Name:	**Merete MetaFix Small Fragment Locking Bone Plate System**
Device Classification:	**21 CFR 888.3030 Single/multiple component Metallic bone fixation appliances and accessories and 888.3040 Smooth /threaded metallic bone fixation fastener.**
Product Code:	**KTT**
Proposed Regulatory Class:	**Class II**
Predicate Device:	**· Synthes Small Fragment Locking Compression Plate (LCP) K000684** **· Smith & Nephew Locking Bone Plate System K033669**
Description of Device:	**The Merete MetaFix Small Fragment Locking Plate System consists of profile T-Oblique plates, right or of various left, of various sizes and 3.0 mm locking screws. The system is available in titanium (ASTM F-136). Locking plates/screws incorporate a screw-to-plate locking feature which creates a locked, fixed angle construction to hold fracture or osteotomy reduction.**
Intended use:	**The Merete MetaFix Small Fragment Locking plateSystem is used for adult and pediatric patients as indicated for small bone fracture fixation. Indications for use include fixation of fractures, osteotomies, non unions of the clavicle, scapula, olecranon, radius, ulner, fibula, metacarpals, metatarsals, Hallux Valgus osteotomy corrections, middle hand and middle foot bones, particular in osteopenic bone.**
Technological Characteristics:	**The components of the Merete MetaFix Small Fragment Locking Plate System are similar to legally marketed predicate devices listed above in that they share similar indications for use, are manufactured from similar materials and incorporate similar technological characteristics.**
Potential Risks:	**The risks associated with this device are the same as with any metallic internal fixation device. These include but not limited to the following: Delayed or nonunion which may lead to breakage the implant. Bending or fracture of the implant. Metal sensitivity, or allergic reaction to a foreign body. Pain, discomfort, or abnormal sensation due to the presence of the device.**

3. Standards

The MetaFix-system is produced from titanium alloy Ti-6Al-4V according to ASTM F-136 and ISO 5832/3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2005

Merete Medical GMBH
c/o Mr. Jenik Radon
269 West Seventy- First Street
New York, New York 10023

Re: K050457
Trade/Device Name: Merete MetaFix Small Fragment Locking Bone Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: February 21, 2005
Received: February 23, 2005

Dear Mr. Radon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050457/A1

Indications for Use
Merete MetaFix Small Fragment Locking Bone Plate System

510(k) Number (if known):_____

Device Name: Merete MetaFix Small Fragment Locking Bone Plate

Indications For Use:

The Merete MetaFix Small Fragment Locking Bone Plate System is used for adult and pediatric patients as indicated for small bone fracture fixation. Indications for use include fixation of fractures, osteotomies, non unions of the clavicle, scapula, olecranon, radius, ulnar, fibula, metacarpals, Halllux Valgus osteotomy corrections, middle hand and middle foot bones, particular in osteopenic bone.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050457